IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Pa.R.C.P. 2202(b) as Trustee ad Litem for the Estate of JESSICA DIANE DAVILA, deceased, Plaintiff, v. GENERAL NUTRITION CENTERS, INC., and GNC HOLDINGS, INC., and USPLABS, LLC Defendants. ORDER	CIVIL ACTION No. 12-CV-3962-TJS
AND NOW, this day of	_, 2012, upon consideration of Plaintiff's
Motion for Remand, it is hereby ORDERED that said	Motion is GRANTED and that this action
is remanded to the Court of Common Pleas, Philadelph	nia County, Commonwealth of
Pennsylvania, where the action shall continue as June	Term, 2012, Civil Action No. 2113.
It is further ORDERED , pursuant to U.S.C. § 1	447(c), that the Clerk of Court shall send
a certified copy of this Order to the Prothonotary of the	e Court of Common Pleas, Philadelphia
County and shall return the file in this action to the Pro	thonotary.
	BY THE COURT:

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SHIRLEY DAVILA, individually and pursuant to : Pa.R.C.P. 2202(b) as Trustee ad Litem for the : Estate of JESSICA DIANE DAVILA, deceased, :

: CIVIL ACTION

No. 12-CV-3962-TJS

Plaintiff,

V.

GENERAL NUTRITION CENTERS, INC., and GNC HOLDINGS, INC., and USPLABS, LLC

MOTION TO REMAND

Defendants.

PLAINTIFF'S MOTION TO REMAND FOR LACK OF SUBJECT MATTER JURISDICTION

Plaintiff, Shirley Davila, by and through her attorneys, Wapner, Newman, Wigrizer, Brecher & Miller, P.C., hereby moves this Honorable Court to Remand the above captioned case to the Court of Common Pleas, Philadelphia County, Commonwealth of Pennsylvania, and in support thereof and in adherence to Administrative Order No. 18, states the following.

- 1. On November 14, 2011, Jessica Diane Davila died as a result of malignant hypothermia caused by the ingestion of OxyELITE PRO (hereinafter as "PRO"), a thermogenic diet pill. (See *Plaintiff's Complaint*, attached hereto as "Ex. A." at ¶ 5.)
- 2. On June 18, 2012, Plaintiff Shirley Davila instituted the instant action against Defendants USPLabs, LLC (hereinafter as "USP"), General Nutrition Centers, Inc. and GNC Holdings, Inc. (collectively hereinafter as "GNC") with state law claims sounding in strict products liability, negligence, and breach of warranty for the defendants' respective roles in the manufacture, distribution, and sale of PRO. (Ex. A.)

- The Civil Action was filed in the Court of Common Pleas, Philadelphia County,
 Commonwealth of Pennsylvania, and docketed as June Term 2012, Civil Action No. 2115. (Ex. A.)
- 4. Plaintiff Shirley Davila, the mother of the deceased, brings this action pursuant to Pa.R.C.P. 2202(b) as Trustee ad Litem for the Estate of Jessica Diane Davila.
- 5. Defendant USP, either itself or jointly, was at all relevant times hereto the manufacturer and distributor of PRO. (Ex. A at ¶ 10.)
- 6. Defendant USP does business in the Commonwealth of Pennsylvania, having an agreement with the GNC defendants to stock and sell PRO in stores throughout the State. (Ex. A at ¶ 11.)
 - 7. The GNC defendants are the main marketer and retailer of PRO. (Ex. A at ¶ 19.)
- 8. Jessica Diane Davila, deceased, purchased the PRO that caused her to suffer malignant hypothermia at a GNC retail location. (Ex. A at ¶¶ 23-24.)
- 9. On July 12, 2012, Defendants filed a Notice of Removal to this Court, relying solely upon the incorrect assertion that this Court has original jurisdiction over Plaintiff's claims under 28 U.S.C. § 1331. (See *Notice of Removal*, attached here to as "Ex. C" (without exhibits).)
- 10. For the reasons stated in the attached Memorandum of Law, the Plaintiff requests this Court remand this civil action to the Court of Common Pleas, Philadelphia County, Commonwealth of Pennsylvania.
- 11. The sole ground relied upon by Defendants in their Notice of Removal is federal question jurisdiction. (Ex. C at ¶ 11.)
- 12. As explained in detail in the attached Memorandum of Law, Defendants' argument is entirely based upon a purely conjectural and inaccurate characterization of Plaintiff's

Complaint as alleging "*numerous* violations" of the Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq.* (Ex. C at ¶ 13 (emphasis added).)

- 13. In fact, the Defendants are unable to point to paragraphs of the Complaint citing any statute within the FDCA because none were alleged, explained, or set out in whole or in part.
- 14. Moreover, Defendants chose not to direct this Court to a single statutory provision of the FDCA in support of the Notice of Removal.
- 15. Furthermore, this Court recently addressed this exact issue in the case of <u>In re</u>

 <u>Avandia Marketing</u>, 2012 U.S. Dist. LEXIS 48319 (E.D.Pa. April 4, 2012). (See Courtesy Copy of Opinion, attached hereto as "Ex. D.")
- 16. In that case, Judge Rufe ruled on a Motion to Remand that was filed in response to a Notice of Removal claiming federal question jurisdiction. <u>Id</u>. The removing party argued that Plaintiffs in that case "repeatedly invoked the federal Food, Drug, and Cosmetic Act in the Complaint." <u>Id</u>. Although that was indeed true in the matter before her, Judge Rufe noted:

[T]he mere presence of a federal statute embedded in a state law cause of action is not sufficient to warrant federal subject matter jurisdiction where there is no federal remedy for a violation of a federal statute. These allegations will not establish [the] ability to recover under the state law claims; instead these allegations relate to possible evidence to support the state-law claims.

[<u>Id</u>. at *12 (emphasis added).]

- 17. For those reasons, Judge Rufe held that: "An assertion of a violation of the FDCA as an element of a state tort claim is not a sufficiently substantial factor to confer federal question jurisdiction." <u>Id.</u> at *14-15.
- 18. Here, as fully developed in the attached Memorandum of Law, the arguments asserted by Defendants in their ill-fated attempt to show that Plaintiff alleges "numerous

violations" of the FDCA, refer entirely to Plaintiff's characterization of PRO as an "adulterated dietary supplement." (Ex. A at ¶¶ 41, 46.)

19. Even assuming arguendo that raises a factual discrepancy over the categorization of PRO under the FDCA, it by no means indicates that Plaintiff's common law claims "arise

under" federal law. Empire Health Assurance, Inc., v. McVeigh, 547 U.S. 677, 690-93 (2006).

20. Instead, Plaintiff's tort and warranty claims state sound and sufficient causes of

action under well-settled Pennsylvania law.

21. For the reasons stated in the attached Memorandum of Law, the removal was

improper and the case should be remanded to the Court of Common Pleas because Defendants'

Notice of Removal falls woefully short of satisfying their "heavy burden" of proving Plaintiff's

complaint presents a federal issue that is actually "substantial and disputed."

22. Pursuant to Local Rule 7.1(f), Plaintiff respectfully requests oral argument on this

matter at the earliest time that is convenient for the Court.

WHEREFORE, Plaintiff respectfully requests that this Court enter the attached Order

remanding this case to the Court of Common Pleas, Philadelphia County where the action shall

continue as June Term 2012, Civil Action No. 2113.

DATED this 6th day of August, 2012.

WAPNER, NEWMAN, WIGRIZER BRECHER & MILLER, P.C.

BY:

STEVENG. WIGRIZER

JASON S. WEISS

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SHIRLEY DAVILA, individually and pursuant to : Pa.R.C.P. 2202(b) as Trustee ad Litem for the : Estate of JESSICA DIANE DAVILA, deceased, :

Plaintiff,

CIVIL ACTION

No. 12-CV-3962-TJS

V.

GENERAL NUTRITION CENTERS, INC., and GNC HOLDINGS, INC., and USPLABS, LLC

Defendants.

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION TO REMAND

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION TO REMAND FOR LACK OF SUBJECT MATTER JURISDICTION

Submitted by:

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QUESTION PRESENTED

1. Under 28 U.S.C. § 1331, whether this case should be remanded to the Pennsylvania Court of Common Pleas, when Defendants cannot satisfy their burden of proffering sufficient facts that Plaintiff's Complaint raises a substantial federal issue?

INTRODUCTION

On November 14, 2011, Jessica Diane Davila, died as a result of malignant hyperthermia caused by the ingestion of OxyELITE PRO (hereinafter as "PRO"), a thermogenic diet pill. (See *Plaintiff's Complaint*, attached hereto as "Ex. A" at ¶ 5.) PRO is an over the counter dietary supplement that contains the ingredient Dimethylamylamine ("DMAA"). (See *Product Image*, attached hereto as "Ex. B.")

On June 18, 2012, Plaintiff Shirley Davila¹ instituted this wrongful death and survival action in the Pennsylvania Court of Common Pleas of Philadelphia County. (Ex. A.) The Complaint alleged causes of action sounding in strict liability, negligence, and breach of warranty against Defendants USPLabs, LLC (hereinafter as "USP"), General Nutrition Centers, Inc. and GNC Holdings, Inc. (hereinafter collectively as "GNC"). (Ex. A ¶¶ 61-74, 82-104.)

As of the time of the filing of the Complaint, defendant USP, either itself or jointly with third parties, was the manufacturer and distributor of PRO. (Ex. A at ¶¶ 10, 19) USP does business in the Commonwealth of Pennsylvania, having an agreement with the GNC Defendants to stock and sell PRO in stores throughout the state. (Ex. A at ¶ 11.)

The GNC defendants are the main marketer and retailer of PRO. (Ex. A at ¶ 19.) Plaintiff's complaint alleges that the employees and sales people of GNC did more than simply stock the product at issue on the shelves of a store. Plaintiff alleges that the GNC defendants were instructed in the marketing and sale of PRO, and as such, had a duty to the decedent to warn her of the risk of injury associated with the product. (Ex. A at ¶ 33.)

Shirley Davila, the mother of the deceased, brings this action pursuant to Pa.R.C.P. 2202 as Trustee ad Litem for the Estate of Jessica Diane Davila. That rule states: "If no action for wrongful death has been brought within six months after the death of the decedent, the action may be brought by the personal representative or by any person entitled by law to recover damages in such action as trustee ad litem on behalf of all persons entitled to share in the damages." Pa.R.C.P. 2202(b).

On July 12, 2012, Defendants filed a Notice of Removal, incorrectly asserting that "[t]his court has jurisdiction over this action pursuant to 28 U.S.C. ¶ 1331 as Plaintiff's Complaint raises issues of federal law and prosecution of Plaintiff's claims against Defendants will require construction of the Federal Food, Drug and Cosmetic Act ["FDCA"] as amended by the Dietary Supplement Health and Education Act of 1994." (See *Notice of Removal*, attached hereto as "Ex. C" at ¶ 18 (without exhibits).) The sole argument advanced by Defendants in their filing was that this Court has "original jurisdiction" pursuant to "a federal question that arises under the laws of the United States." (Ex. C at ¶ 11).

In support of their filing, the Defendants boldly assert that "the Plaintiff bases her claim for relief against the Defendants upon *numerous* violations of" the FDCA. (Ex. C at ¶ 13 (emphasis added).) However, as developed *infra*, that statement is categorically incorrect. Instead, the only allegations of Plaintiff's Complaint that could be inferred to incorporate the FDCA reads as follows: (1) "Defendant USP improperly claims that the PRO product is a legal dietary supplement;" and (2) "PRO is an adulterated dietary supplement as that term is defined in the Food, Drug and Cosmetic Act." (Ex. A at ¶ 41, 46.) In fact, the Defendants are unable to point to paragraphs of the Complaint citing any statute within the FDCA because none were alleged, explained, or set out in whole or in part. Moreover, Defendants chose not to direct this Court to a single statutory provision of the FDCA in support of the Notice of Removal.

The arguments advanced in the Notice of Removal are insufficient to permit

Defendants to satisfy their burden of establishing subject matter jurisdiction. In addition, any
exercise of federal jurisdiction would disturb the balance of federal and state judicial duties
and responsibilities. As such, removal is improper and this case should be remanded.

STANDARD OF REVIEW

A defendant may remove a civil action filed in state court if the federal court to which it is removed would have had "original jurisdiction" over the action. 28 U.S.C. § 1441(a). However, it is well-settled that the removal statutes "are to be strictly construed against removal and all doubts should be resolved in favor of remand." Boyer v. Snap-On Tools Corp., 913 F.2d 108, 111 (3d Cir. 1990).

The statutory requirement that there be original jurisdiction mandates that the question involving federal law "must be disclosed upon the face of the complaint, unaided by the answer or by the" removal notice. <u>Gully v. First Nat'l Bank</u>, 299 U.S. 109, 112 (1936).

Absent diversity jurisdiction, a civil action filed in state court may only be removed if a claim arises under federal law. <u>Westmoreland Hosp. Ass'n v. Blue Cross of Western Pa.</u>, 605 F.2d 119, 123 (3d Cir. 1979). Whether the claim arises under federal law generally must be determined by applying the "well-pleaded complaint rule, which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint." <u>Caterpillar, Inc. v. Williams</u>, 482 U.S. 386, 392 (1987).

As the parties removing the case, USP and GNC bear a heavy burden to prove that federal jurisdiction is proper at all stages of the litigation. <u>Samuel Basset v. Kia Motors Am.</u>, <u>Inc.</u>, 357 F.3d 392, 396 (3d Cir. 2004). As developed below, Defendants cannot satisfy this burden.

ARGUMENT

A. Plaintiff's Motion To Remand Should Be Granted Because Defendants Have Failed To Satisfy Their Burden Of Demonstrating That This Court Has Subject Matter Jurisdiction Over Plaintiff's Claims.

Defendants' Notice of Removal falls woefully short of meeting the "heavy burden of persuasion" required to prove that this Court has original jurisdiction under 28 U.S.C. § 1331. Steel Valley Auth. v. Union Switch & Signal Div., 809 F.2d 1006, 1010 (3d Cir. 1987). (citations omitted). There is no "mechanical test for determining when an action arises under federal law." Franchise Tax Bd. Of Cal. v. Const. Laborers Vacation Trust, 463 U.S. 1, 8 (1983). However, it is generally accepted that the "well-pleaded complaint" must establish either: (a) that "federal law creates the cause of action;" or (b) that "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." Empire Health Assurance, Inc., v. McVeigh, 547 U.S. 677, 690 (2006).

"Arising under' federal question jurisdiction is generally appropriate in two types of actions." In re: Avandia Marketing, Sales Practices and Products Liability Litigation, 2012 U.S. Dis. LEXIS 48319 at *5 (E.D.Pa. April 4, 2012). The first, most common, form of federal question jurisdiction occurs when the plaintiff pleads a cause of action created by federal law. See, e.g., Metro Life Ins. Co. v. Price, 501 F.3d 271, 276 (3d Cir. 2007) ("Federal question jurisdiction exist when the plaintiff's well-pleaded complaint establishes that federal law creates the cause of action.") As previously stated, Defendants have failed to set forth a single statutory section of the FDCA in support of their Notice of Removal. (Ex. C.)

Accordingly, this type of federal question jurisdiction is not applicable to the case at bar.

In the second, much rarer form of "arising under" jurisdiction, the plaintiff's state law cause of action necessarily is plead in a manner that "implicates significant federal issues" or

"turns on substantial questions of federal law" and therefore contains an "embedded federal issue." Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 312, 318 (2005). In such a case, it is well-settled that even if the state law based action discloses a substantial and disputed federal issue, federal jurisdiction is subject to a possible veto. Id. at 312. Instead, the federal issue will ultimately qualify for a federal forum only if jurisdiction is consistent with congressional judgment about the sound division of labor between state and federal courts. Id. Thus, the analysis turns on whether "a state-law claim necessarily raises a stated federal issue, *actually disputed and substantial*, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." Id. at 314 (emphasis added).

The mere existence of a federal defense to a state law cause of action is insufficient for a moving defendant to satisfy its heavy burden. <u>Caterpillar</u>, 482 U.S. at 393. Instead, "the plaintiff's well-pleaded complaint must include . . . an explicit cause of action or a state-law cause of action that contains an embedded federal question that is both substantial and disputed." <u>In re: Avandia Marketing</u>, 2012 U.S. Dist. LEXIS at *6-7 (citations omitted).

Accordingly, jurisdiction will lie in federal court only if three conditions are met: (1) the case necessarily raises a federal issue; (2) the federal issue is substantial and in actual dispute; and (3) the exercise of federal jurisdiction will not disturb "any congressionally approved balance of federal and state judicial responsibilities." Grable, 545 U.S. at 314. The Supreme Court has held that if the dispute does not rely solely upon a determination of federal law, remand is appropriate. Empire, 547 U.S. at 691-93.

In this case, the pleadings reveal that USP and GNC have failed to satisfy those three conditions.

1. A reference to the Food, Drug and Cosmetic Act does not implicate a federal issue that is "substantial and disputed."

Defendants Notice of Removal was premised upon what was categorized as "numerous violations" of the FDCA alleged in Plaintiff's Complaint. (Ex. C. at ¶ 13.) In support of this erroneous contention, Defendants point to four specific paragraphs of Plaintiff's Complaint. (Ex. C at ¶¶ 14-17.) Those paragraphs read, in their entirety, as follows:

- 41. Defendant USP improperly claims that the PRO product is a legal dietary supplement.
- 42. Contrary to the statements on the label of the PRO product, it contains a form of Dimethylamylamine known as DMAA
- 45. The DMAA ingredient in PRO is manufactured synthetically, and therefore unlawfully on the market as an ingredient in OxyELITE Pro.
- 49. Regardless of the precise characterization of PRO, or the precise characterization of the DMAA contained in PRO, by engaging in the manufacturing, distribution, selling and/or supplying of PRO, ALL DEFENDANTS have violated relevant rules, regulations and/or statutes related to the Product.

(Ex. A at \P 41, 42, 45, 49.)

Even assuming *arguendo* that Defendants contention had some remote support, the argument itself overlooks the standard utilized in this Court. That rule of law, which was recently reinforced by the Hon. Cynthia M. Rufe, provides that: "The fact that a complaint mentions, *or even incorporates* federal law, does not determine whether it 'arises under' the Constitution, laws or treaties of the United States." <u>In re: Avandia Marketing</u>, 2012 U.S. Dist. LEXIS 48319 at *7 (emphasis added); <u>see also Fairfax Fin. Holdings, Ltd. v. S.A.C.</u>, 2007 U.S. Dist. LEXIS 39214 at *3 (D.N.J. May 15, 2007) ("The Complaint does not 'necessarily raise' a federal question because it alleges predicate violations of both federal and state laws").

A review of Plaintiff's Complaint clearly reveals that the reference to PRO as an "adulterated dietary supplement" is one part of the evidence to support all state law claims alleged. Plaintiff submits that an assertion of a violation of the FDCA as an element of a state tort claim is not a sufficiently substantial federal issue to confer federal question jurisdiction.

Earlier this year this Court was faced with a similar issue in In Re: Avandia

Marketing, Sales Practices and Products Liability Litigation (See *Opinion*, attached hereto as "Ex. D.") In a Memorandum Opinion issued April 4, 2012, Judge Rufe ruled on a Motion to Remand that was filed in response to a Notice of Removal claiming federal question jurisdiction. Id. The removing party argued that Plaintiffs in that case "repeatedly invoked the federal Food, Drug, and Cosmetic Act in the Complaint." Id. Although that was indeed true in the matter before her, Judge Rufe noted:

[T]he mere presence of a federal statute embedded in a state law cause of action is not sufficient to warrant federal subject matter jurisdiction where there is no federal remedy for a violation of a federal statute. These allegations will not establish [the] ability to recover under the state law claims; instead these allegations relate to possible evidence to support the state-law claims.

[Id. at *12 (emphasis added).]

For those reasons, Judge Rufe held as follows: "An assertion of a violation of the FDCA as an element of a state tort claim is not a sufficiently substantial factor to confer federal question jurisdiction." <u>Id.</u> at *14-15.

The issue raised here by Defendants in their Notice of Removal is analogous with that presented in In re: Avandia Marketing. Defendants have cherry-picked a portion of the Complaint in an attempt to show that violations of the FDCA are the gravamen of Plaintiff's claims. This is simply untrue. In reality, Plaintiff's claims sound in strict products liability, negligence, and breach of warranty under Pennsylvania state law. If USP and GNC

manufactured, distributed, and sold PRO in violation of any section of the FDCA, those violations will merely help Plaintiff to satisfy the elements of her state law claims. As stated by Judge Rufe, "these allegations relate to possible evidence to support the state-law claims." Id. at *12.

Accordingly, this Court should grant Plaintiff's motion because the mere reference of the FDCA in the Complaint does not implicate a federal issue that is substantial and disputed.

2. Plaintiff's tort law claims are based upon Pennsylvania state law.

Even assuming *arguendo* this Court was to find that Plaintiff's classification of PRO as an "adulterated dietary supplement" was a factual inquiry that necessarily incorporated the FDCA, remand would still be appropriate. Empire, 547 U.S. at 691-93. It is undisputed that Plaintiff's main claims sound in strict products liability and negligence. Further, it cannot be argued that Plaintiff's basis for these common law causes of action is based upon the language of the FDCA.

The easiest way to articulate this point is to analyze Plaintiff's failure to warn claim. According to the FDCA, as well as the amendments to it found in the Dietary Supplement Health and Education Act, the inclusion of product warnings on a dietary supplement product is permitted and encouraged, *but not required*. Thus, any failure to warn claim, whether sounding in strict liability or negligence, must be proved in the context of state law.

In 1966, Pennsylvania adopted Section 402(A) of the *Restatement (Second) of Torts* as the governing law in products liability cases. Webb v. Zern, 422 Pa. 424 (Pa. 1966). To recover under a strict liability claim brought pursuant to Section 402(A), a plaintiff must establish: (1) that the product was defective; (2) that the defect was a proximate cause of the

plaintiff's injuries; and (3) that the defect causing the injury existed at the time the product left the seller's hands. <u>Davis v. Berwind Corp.</u>, 547 Pa. 260, 690 A.2d 186, 189-90 (1997).

"It is well settled that a dangerous product can be considered 'defective' for strict liability purposes if it is distributed without sufficient warnings to notify the ultimate user of the dangers inherent in the product." Mackowick v. Westinghouse Electric Corp., 525 Pa. 52, 575 A.2d 100, 102 (1990). Although the black letter rule set forth in Section 402(A) does not explicitly provide for a failure to warn claim, comment j to the rule states that: "in order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning on the container as to the use." Restatement (Second of Torts) § 402(A), comment j (1965); see also Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206 (1971) (adopting comment j in Pennsylvania).

In order to establish a *prima facie* case of failure to warn, a plaintiff must establish two elements: (1) that that the lack of an adequate warning rendered the product *defective*; and (2) that the lack of an adequate warning was the *proximate cause* of the accident. Morris v. Pathmark Corp., 405 Pa. Super. 274, 277 (1991), allocator granted, 530 Pa. 664, appeal dismissed, 536 Pa. 104 (1994).

Here, Plaintiff is asserting that PRO did not contain an adequate warning of malignant hypothermia that was posed to regular users of the product, including Jessica Diane Davila. Further, Plaintiff is asserting that if PRO contained an adequate warning that Jessica Diane Davila would not have used the product and consequently, would not have died on November 14, 2011. (Ex. A at ¶ 33.) Stated simply, Plaintiff's failure to warn claim has nothing to do with the label encouragements set forth in the FDCA.

This is because in order to prove a strict liability claim for failure to warn under Section 402(A), a plaintiff must prove he is an intended "consumer" or "user" of the product. Product warnings "must be directed to the understanding of the intended user." Mackowick, 575 A.2d at 102. "A warning of inherent dangers is sufficient if it adequately notifies the intended user of the *unobvious* dangers inherent in the product." <u>Id</u>. at 102-03 (emphasis in original).

The comments to section 402(a) define "user" and "consumer" as follows:

In order for the rule stated in this Section to apply, it is not necessary that the ultimate user or consumer have acquired the product directly from the seller, although the rule applies equally if he does so . . .

"Consumers" include not only those who in fact consume the product, but also who prepare it for consumption . . . Consumption includes all ultimate uses for which the product is intended . . .

"User" includes those who are passively enjoying the benefit of the product, as in the case of passengers in automobiles or airplanes, as well as those who are utilizing it for the purpose of doing work upon it, as in the case of an employee of the ultimate buyer who is making repairs upon the automobile, which he has purchased.

[Restatement (Second) of Torts \S 402(A), comment 1 (emphasis added).]

In this case, it is clear that Jessica Diane Davila was a consumer of the product. It is similarly indisputable that she was an "intended user" of a product marketed as a diet pill.

Moreover, a product may be found to be "defective" even if it conforms to its intended design. Azzarello v. Black Bros. Co., Inc., 540 Pa. 547, 555 (Pa. 1978). Under these theories of strict liability, the critical factor is whether it can be said the product qualifies as "unreasonably dangerous." Id. However, when undergoing this analysis, the "social policy" involved with the Court's risk-utility analysis is "relatively simple" in failure to warn cases. Hon v. Stroh Brewery Co., 835 F. 2d 510, 513 (3d Cir. 1987). This is because "the cost of

adding a warning, or of making an inadequate warning adequate, will at least in most cases be outweighed by the risk of harm if there is no adequate warning." <u>Id</u>.

Therefore, the fact that FDCA does not require warnings has no relevance to Plaintiff's strict liability failure to warn claim. Similarly, an argument that PRO was manufactured in adherence with the FDCA would not prevent a jury from determining that the product was unreasonably dangerous.

Similarly, a plaintiff's burden of proof on a negligence claim for failure to warn is "to show that the defendant had a duty to conform to a certain standard of conduct, that the defendant breached that duty, that such breach caused the injury in question, and actual loss or damage." Phillips v. Cricket Lighters, 576 Pa. 644, 841 A.2d 1000, 1008 (Pa. 2003). In the products liability context, the duty of care arises where a reasonable jury might find that the defendant is a manufacturer, seller, or distributor of the allegedly defective product. Mellon v. Barre-National Drug Co., 431 Pa. Super. 175, 182-183 (Pa. Super. 1993). Here it cannot be disputed that USP manufactured PRO nor that GNC was a seller of the product.

Accordingly, the Court must remand this case because Plaintiff's strict liability and negligence claims do not arise under federal law.

3. Plaintiff's warranty claims are based upon Pennsylvania state law.

Plaintiff's claims of breach of express and implied warranty are not governed by the FDCA, but are grounded in state law. (Ex. A ¶¶ 85-93). In order to prevail on these claims, Plaintiff will be required to present proofs in accordance with settled law developed in the Pennsylvania State Courts.

It is longstanding precedent in Pennsylvania that a buyer purchasing a product is deemed to have relied upon the retailer's judgment in selecting the item. <u>Bonenberger v.</u>

<u>Pittsburgh Merchantile Co.</u>, 345 Pa. 559 (Pa. 1943). Therefore, an express warranty exists between retailer and consumer establishing that the item is safe for purchase and its intended use. Id.

Pennsylvania likewise permits recovery for economic injuries for breach of an implied warranty. Weiler v. Smithkline Beecham Corp., 53 Pa. D. & C.4th 449, 464 (Pa. Cmwlth. 2001) (citing Altronics of Bethlehem Inc. v. Repco Inc., 957 F.2d 1102, 1106-1107 (3d Cir. 1992)). Under Pennsylvania law, the sale of goods may include implied warranties of merchantability and fitness for a particular purpose. 13 Pa.C.S. §§ 2314, 2315.

To recover, Plaintiff must show a violation of Section 2314 of the Pennsylvania Commercial Code, which sets forth the implied warranty of merchantability as follows: "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." 13 Pa.C.S. § 2314(a).

The Statute further provides that goods to be merchantable must be at least as such as:

- (1) pass without objection in the trade under the contract description;
- (2) in the case of fungible goods, are of fair average quality within the description;
- (3) are fit for the ordinary purposes for which such goods are used;
- run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved;
- (5) are adequately contained, packaged, and labeled as the agreement may require; and
- (6) conform to the promises or affirmations of fact made on the container or label if any.

[13 Pa.C.S. § 2314(b).]

If any of those standards are not met, there is a breach of the implied warranty of merchantability. <u>Infocomp, Inc. v. Electra Products, Inc.</u>, 109 F.3d 902, 908 (3d Cir. 1997).

Defendants cannot point to a single reference in the FDCA that would suggest or support the warranty claims, or the standard of proof necessary to succeed on each. The most

that can be said is that a broadly interpreted assertion that the FDCA's definition of "adulterated dietary supplement" as one element of the state law based claims is not a sufficiently substantial federal issue to confer federal question jurisdiction. <u>In re: Avandia</u> Marketing, at *12-15.

Accordingly, Plaintiff's motion must be granted because it is clear that her causes of action sounding in breach of warranty do not arise under federal law.

CONCLUSION

The burden of demonstrating federal question jurisdiction rests upon Defendants.

Federal jurisdiction must appear on the face of the complaint and cannot be inferred from any proposed defense. Here, the Plaintiff has alleged violations of state law under state statutes and state common law. These state law causes of action do not implicate significant federal issues or turn on substantial questions of federal law. The application of federal jurisdiction in this matter would upset the balance of federal and state judicial responsibilities, and would not be consistent with congressional judgment about the sound division of labor between state and federal courts.

Accordingly, Plaintiff respectfully requests that this Court find that federal jurisdiction is not present, and remand this case to the Court of Common Pleas, Philadelphia County.

WAPNER, NEWMAN, WIGRIZER BRECHER & MILLER P.C.

BY:

STEVEN G. WIGRIZER

Attorneys for Plaintiff

BY: STEVEN G. WIGRIZER JASON S. WEISS

wigrizers@wnwlaw.com/weissj@wnwlaw.com

Identification No. 30396/310446 WAPNER, NEWMAN, WIGRIZER, BRECHER & MILLER, P.C.

2000 Market Street, Suite 2750 Philadelphia, PA 19103 (215) 569 - 0900 ATTORNEYS FOR PLAINTIFF

SHIRLEY DAVILA, Individually and pursuant to : Pa.R.C.P. 2202(b) as Trustee Ad Litem for the :

Estate of JESSICA DIANE DAVILA, deceased

COURT OF COMMON PLEAS PHILADELPHIA COUNTY

Plaintiffs

CIVIL ACTION

V.

GENERAL NUTRITION CENTERS, INC.

and

JUNE TERM, 2012

GNC HOLDINGS, INC.

and

NO. 002113

USPLABS, LLC

Defendants

CERTIFICATE OF SERVICE

I, Jason S. Weiss, attorney for plaintiff, hereby states that a true and correct copy of Plaintiff's Motion to Remand has been provided via first class U.S. mail to the following:

William C. Mills, Esquire Weber Gallagher Simpson Stapleton Fires & Newby, LLP

2000 Market Street 13th Floor

Philadelphia, PA 19103

WAPNER, NEWMAN, WIGRIZER BRECHER & MILLER, P.C.

BY:

STEVEN G. WIGRIZER

JASON S. WEISS

Attorneys for Plaintiff

EXHIBIT A

Court of Common Pleas of Philadelphia County Trial Division

Civil Cover Sheet

For Prothonotary Use Only (Docket Number)

JUNE 2012

002113

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PLAINTIFF'S NAME SHIRLEY DAVILA			DEFENDANTS NAME GENERAL NUTRITION CENTERS, INC.			
PLAINTIFFS ADDRESS 619 POPLAR STREET ABILENE TX 79602		DEFENDANTS ADDRESS 2001 MARKET STREET 5TH FLOOR PHILADELPHIA PA 19103				
PLAINTIFF'S NAME		DEFENDANT'S NAM				
PLAINTIFF'S ADDRESS 619 POPLAR STREET ABILENE TX 79602 PLAINTIFF'S NAME		DEFENDANTS ADDRESS 2001 MARKET STREET 5TH FLOOR PHILADELPHIA PA 19103				
		DEFENDANTS ADDRESS 10761 KING WILLIAM DRIVE DALLAS TX 75220				
		TOTAL NUMBER OF PLAINTIFFS	TOTAL NUMBER OF DEFENDANTS	COMMENCEMENT OF ACTION	ON	
2	3	Complaint	Petition Action	☐ Notice of Appeal		
		☐ Writ of Summons	Transfer From Other Jur	isdictions		
	OURT PROGRAMS Arbitration	Mass Tort				
1 \$50,000,00		Savings Action	Commerce Minor Court Appeal	Settlement Minors		
	Non-Jury	Petition	Statutory Appeals	☐ W/D/Survival		
CASE TYPE AND CODE	**************************************					
2P - PRODUCT LIABI	LITY					
STATUTORY BASIS FOR CAUSE OF ACT	10N	Service and a service of the service				
RELATED PENDING CASES (LIST BY CA	SE CAPTION AND DOCKET NUMBER)	FILED PROTHY		UBJECT TO THON ORDER? YES NO		
		JUN 18 2012				
		J. MURPHY				
TO THE PROTHONOTARY	γ:					
Kindly enter my appearance of	on behalf of Plaintiff/Petitione	r/Appellant: SHIRLE	Y DAVILA , SHIRL	EY DAVILA		
Papers may be served at the a						
NAME OF PLAINTIFF'S/PETITIONER'S/API STEVEN G. WIGRIZER	PELLANT'S ATTORNEY		ET STREET			
PHONE NUMBER (215)569-0900	FAX NUMBER (215) 569-4621		SUITE 2750 PHILADELPHIA PA 19103			
SUPREME COURT IDENTIFICATION NO.		E-MAIL ADDRESS Wigrizers	@wnwlaw.com			
SIGNATURE OF FILING ATTORNEY OR PA STEVEN WIGRIZER	RTY	DATE SUBMITTED	uno 10 2012 11	. 4.4		

BY: STEVEN G. WIGRIZER JASON S. WEISS

wigrizers@wnwlaw.com/weissj@wnwlaw.com Identification No. 30396/310446 WAPNER, NEWMAN, WIGRIZER, BRECHER & MILLER, P.C.

2000 Market Street, Suite 2750 Philadelphia, PA 19103 (215) 569 - 0900

SHIRLEY DAVILA, Individually and pursuant to:
Pa.R.C.P. 2202(b) as Trustee Ad Litem for the
Estate of JESSICA DIANE DAVILA, deceased
619 Poplar Street
Abilene, TX 79602

Plaintiff,

v.

GENERAL NUTRITION CENTERS, INC., 2001 Market Street, 5th Floor Philadelphia, PA 19103

and

GNC HOLDINGS, INC. 2001 Market Street, 5th Floor Philadelphia, PA 19103

and

USPLABS, LLC 10761 King William Drive Dallas, TX 75220

Defendants.

This is a Major Jury Case.

Jury Trial is Demanded.

Assessment of Damages Haaring Leauned by PROTHONOTARY ATTORNEYS FOR PLAIS 11 F

COURT OF COMMON PLEAS PHILADELPHIA COUNTY

CIVIL ACTION

CIVIL ACTION COMPLAINT 2P - PRODUCT LIABILITY

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering awritten appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene venite (20) dias de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrite sus defensas o sus objectiones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará mididas y

against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION

LAWYER REFERRAL AND INFORMATION SERVICE ONE READING CENTER PHILADELPHIA, PA 19107 TELEPHONE: (215) 238-6333 puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATA-MENTE. SI NO TIENE ABOGADO O SINO TIENE EL DI-NERO SUFICIENTE DE PAGAR TAL SERVICO, VAYA EN PERSONA O LLAME POR TELEPHONO A LA OFICINA CUYA DIRECCIÓN SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUDE CONSEGUIR ASISTENCIA LEGAL.

ASOCIACIÓN DE LICENCIADOS DE FILADELFIA

SERVICIO DE REFERENCIA E INFORMACIÓN LEGAL ONE READING CENTER FILADELFIA, PA 19107 TELÉFONO: (215) 238-6333

COMPLAINT - CIVIL ACTION

PRELIMINARY STATEMENT

- 1. This is an action for damages against GENERAL NUTRITION CENTERS, INC., and GNC HOLDINGS, INC (hereinafter collectively as "GNC") and USPLABS, LLC (hereinafter "USP") related to the design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of OxyELITE Pro (hereinafter "PRO") by said Defendants.
- Plaintiff SHIRLEY DAVILA is an adult citizen and resident of the State of Texas, residing at the above address.
- SHIRLEY DAVILA is the surviving mother of JESSICA DIANE DAVILA, deceased.
- 4. Pursuant to the Pennsylvania Rules of Civil Procedure, SHIRLEY DAVILA is the proper representative of the Estate of JESSICA DIANE DAVILA as the deceased's Trustee ad Litem pursuant to Pa.R.C.P. 2202(b).
- 5. JESSICA DIANE DAVILA died on November 14, 2011 as the result of malignant hyperthermia due to consumption of the Product, a thermogenic diet pill.
 - 6. There are no debts of the Estate of JESSICA DIANE DAVILA.
- 7. There is no administration of the Estate of JESSICA DIANE DAVILA pending and none is necessary.
- 8. Defendant USP has its principal place of business located at 2221 Manana Drive, Suite 120, Dallas, Texas, 75220.
- 9. Defendant USP's agent for service of process is Johnathan Doyle, who is located at the above address.

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- 10. Defendant USP manufactures itself or jointly with third party manufacturers and distributes, packages, delivers, sells, and markets PRO "ultra-premium" supplement.
- 11. Defendant USP does business in the state of Pennsylvania, and has an agreement with GNC and related entities to stock and sell its products, including PRO, in stores throughout the United States of America, including in Philadelphia, Pennsylvania.
- 12. Defendant GENERAL NUTRITION CENTERS, INC., and its related entities and/or subsidiaries had at all material times a licensing, distribution and marketing agreement with Defendant USP for the distribution and sales of the Product.
- 13. Defendant GENERAL NUTRITION CENTERS, INC., is a corporation organized and existing under the laws of the State of Delaware, with its principal executive offices at 300 Sixth Avenue, Pittsburgh, Pennsylvania 15222.
- 14. Defendant GENERAL NUTRITION CENTERS, INC., is a holding company that conducts all of its operation through its operating subsidiaries.
- 15. Defendant GENERAL NUTRITION CENTERS, INC., is the largest nationwide specialty retailer of vitamin, mineral, and other like supplements, as well as sports nutrition products, as well as many other personal care and related products including PRO.
- 16. Defendant GNC HOLDINGS, INC., a known subsidiary of defendant GENERAL NUTRITION CENTERS, INC., has its registered office address care of CT Corporation System, in Philadelphia, Pennsylvania, located at the above address, where it may be served with service of process.
- 17. In the form 10-K filed by GNC for the year ended December 31, 2010, filed with the Securities and Exchange Commission on February 25, 2011 it states that GNC has 2748 domestic, company owned retail locations including 153 company-owned retail locations and 31

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franchise locations in the State of Pennsylvania.

- 18. GNC regularly conducts business in Philadelphia County, having registered addresses in at least ten (10) locations in the city of Philadelphia, including at the addresses of 1711 Chestnut Street, Philadelphia, PA 19102 and 2955 Market Street, Philadelphia, PA 19103.
- 19. At all relevant times, Defendant USP was engaged in the business of manufacturing, packaging, marketing, distributing, promoting, and the sale of PRO, and GNC was likewise in the business of promoting, marketing, and selling PRO.
- 20. At all relevant times, ALL DEFENDANTS recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of PRO; and, advertised, promoted, marketed, sold and distributed PRO, as a safe product, when in fact, the Defendants had reason to know, and/or did know, that PRO was not safe for its intended purposes, and that PRO caused serious medical problems, and in certain patients, catastrophic, life threatening, injuries.
- 21. The individual and/or combined acts and/or omissions of GNC and USP resulted in the indivisible injury and ultimate untimely and senseless death of JESSICA DAVILA.
- 22. Each of the above-named Defendants is a joint tortfeasor and is jointly and severally liable to the Plaintiff for the negligent acts and omissions alleged herein.

FACTUAL ALLEGATIONS COMMON TO ALL DEFENDANTS

- 23. Plaintiff's decedent, JESSICA DIANE DAVILA, bought PRO from a GNC branded store, and subsequently began taking PRO, in 2011 and 2012.
- 24. JESSICA DIANE DAVILA bought PRO on more than one occasion from a store owned and operated by defendant GNC.

- 25. JESSICA DIANE DAVILA continued to use PRO in a reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold by GNC and USP, until her death on or about November 14, 2011.
- On or about November 14, 2011, as a direct and proximate result of using PRO,
 JESSICA DIANE DAVILA suffered malignant hypertension.
- 27. As a result of the malignant hypertension caused by ingestion of PRO, JESSICA DIANE DAVILA suffered a tragic, painful and needless death.
- 28. Plaintiff's decedent's death resulted in an incredible ordeal marked by expensive and intensive medical care and treatment prior to her death.
- 29. The reaction and resulting injuries and her untimely death were caused by JESSICA DIANE DAVILA's ingestion of this dangerous product, PRO.
- 30. Plaintiff's Decedent was not aware that her injuries and damages directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations or from her ingestion and/or use of PRO.
- 31. Plaintiff's Decedent could not have reasonably known nor could have learned through reasonable diligence that her injuries and damages directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations or from her ingestion and/or use of PRO.
- 32. Defendants GNC and USP knew, should have known, or could have learned through reasonable diligence that the reaction and resulting injuries could have and did directly result from Plaintiff's Decedent's ingestion of PRO.

- 33. JESSICA DIANE DAVILA would not have purchased and used PRO had the Defendants properly disclosed the risks associated with this supplement, including the risk of injury and death.
- 34. Employees and sales people of the GNC defendants were instructed in the marketing and sale of this product, and as such had a duty to her regarding the disclosures of risk.
- 35. As a direct and proximate result of the Defendants failure to warn about the serious and potentially life threatening effects, JESSICA DIANE DAVILLA, sustained damages and death as alleged.
- 36. As a direct and proximate result of Defendants' negligence willful, wanton and otherwise culpable acts as described, JESSICA DIANE DAVILA sustained permanent injuries, damages, and an untimely death.
- 37. These injuries and damages have caused Plaintiff's decedent extensive pain and suffering and severe emotional distress prior to her painful and wholly needless death.
- 38. ALL DEFENDANTS failed to warn and/or adequately warn consumers, including Plaintiff's Decedent, of the potential for experiencing cardiac injuries, among others.
- 39. If Defendant USP had performed adequate testing and studies prior to or after the market launch of PRO, it would have been seen that the risk of injury was present and foreseeable.
- 40. Regardless of the Defendants' failure to perform adequate pre-market launch studies, in light of their knowledge from medical literature and post-market adverse event reports, each Defendant failed to adequately warn of the dangers associated with ingredients contained in the product.

- 41. Defendant USP improperly claims that the PRO product is a legal dietary supplement.
- 42. Contrary to the statements on the label of the PRO product, it contains a form of Dimethylamylamine known as DMAA.
- 43. This product is a synthetic form that is illegal and unreasonably dangerous to consumers such as JESSICA DIANE DAVILA.
- 44. The statements made by USP are misleading and the research relied upon by Defendant USP is inadequate and flawed with respect to the safety and efficacy claims made.
- 45. The DMAA ingredient in PRO is manufactured synthetically, and therefore unlawfully on the market as an ingredient in OxyELITE Pro.
- 46. PRO is an adulterated dietary supplement as that term is defined in the Food, Drug and Cosmetic Act.
- 47. If DMAA is instead naturally extracted from a geranium plant, DMAA by virtue of its inclusion in the PRO product, makes the product nevertheless "adulterated" and therefore unlawfully on the market.
- 48. Defendant USP's PRO product contains DMAA as a synthetic, as such it cannot be a constituent of a botanical.
- 49. Regardless of the precise characterization of PRO, or the precise characterization of the DMAA contained in PRO, by engaging in the manufacturing, distribution, selling and/or supplying of PRO, ALL DEFENDANTS have violated relevant rules, regulations and/or statutes related to the Product.

- 50. Concern about the safety of DMAA in a product such as PRO has become so widespread that the Department of Defense removed the product from its commissaries and outlets.
- 51. The Defendants knew or should have known that PRO when used alone or in combination with other food products created risks of serious injuries or disorders, as to which the Defendants failed to make proper, reasonable or adequate warning to the public and physicians about the risks associated with the use of their product.
- 52. At all times material hereto, the Defendants knew or should have known of the dangerous, life threatening risks associated with the product.
- 53. At all times material hereto, the Defendants proceeded to or permitted PRO to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold without adequate warnings of the serious side effects and dangerous, life threatening risks.
- 54. The Defendants failed to adequately warn the Plaintiff and Plaintiff's Decedent, and other consumers, of the potential serious dangers which they knew or should have known might result from consuming the product.
- 55. Upon information and belief, the Defendants, as a result of the manufacturing and marketing of this product, have reaped profits while failing to adequately warn of the potential hazard associated with the ingestion.
- 56. Prior to the manufacturing, sale and distribution of PRO, the Defendants, through their respective officers, directors and managing agents, had notice as well as knowledge from several sources that the product had substantial and unreasonable risks of harm to consumers.

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- 57. Despite such knowledge, the Defendants, through their respective officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to properly warn the Plaintiff's Decedent, patients, consumers and the public of the serious risk of injury because of the use of PRO.
- 58. As a result of the negligent acts and/or omissions attributed to ALL DEFENDANTS, Plaintiff's decedent died on November 14, 2011 as aforesaid.
- 59. As a result of the negligent acts and/or omissions attributed to each of the defendants and/or their ostensible agents, agents, servants, officers and/or employees, Plaintiff's decedent sustained severe injuries *prior* to her death, including, but not limited to:
 - a. Physical pain;
 - b. Suffering; and
 - c. Mental distress.
- 60. All of the Plaintiff's decedent's aforementioned injuries, which occurred both before and after death:
 - a. Have prevented Plaintiff's decedent from engaging in and enjoying the normal activities of life:
 - b. Will prevent Plaintiff's decedent from engaging in and enjoying the normal activities of life in the future:
 - Have prevented Plaintiff's decedent from attending to her usual duties,
 activities and occupations, causing a loss of earnings;
 - d. Will prevent Plaintiff's decedent from attending to her usual duties, activities
 and occupations in the future causing a loss of earning capacity; and

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e. Have required Plaintiff's decedent's Wrongful Death beneficiaries to spend money and incur obligations in an effort to treat and care for the aforementioned injuries.

COUNT TWO Plaintiff v. All Defendants STRICT PRODUCT LIABLITY (Section 402A)

- 61. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleged as follows.
- 62. Plaintiff avers that Defendants are strictly liable under Section 402A of the Restatement of Torts (Second) for the following reasons:
 - a. At all times relevant to this action, Defendant USP designed, tested,
 manufactured, packaged, marketed, distributed, promoted, and sold PRO,
 placing the drug into the stream of commerce.
 - b. At all times relevant to this action, the GNC Defendants marketed, promoted, distributed and sold PRO was expected to and did reach Plaintiff's Decedent without substantial change in the condition in which it was manufactured and sold. This product was unsafe for normal or reasonably anticipated use.
 - c. PRO was defective in design or formulation because when it left the hands of the respective manufacturer and/or supplier, it was more unreasonably dangerous and more dangerous than an ordinary consumer would expect.
 - d. PRO was also defective and unreasonably dangerous in that the foreseeable risk of injuries from PRO exceeded the benefits associated with the design and/or formulation of the product.

- e. PRO was unreasonably dangerous: a) in construction or composition; b) in design; and c) because the product does not conform to an express warranty of the manufacturer about the product.
- f. PRO as manufactured, marketed and supplied was also defective due to inadequate warnings, clinical trials, testing and study.
- g. PRO as manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use and/or ingestion, they failed to provide adequate warnings to the medical community and the consumers, to whom they were directly marketing and advertising; and, further, they continued to affirmatively promote PRO as safe and effective.
- h. PRO was manufactured, distributed, tested, sold, marketed, advertised and promoted defectively by Defendants. Information given by Defendants to consumers concerning the safety and of PRO, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects.
- Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by use and ingestion of PRO.
- 63. Defendants breached their duties as a designer, manufacturer, seller, and/or supplier under Section 402A of the Restatement of Torts (Second) by:
 - Designing, manufacturing, selling, and/or supplying a product that was unreasonably dangerous;

- Designing, manufacturing, selling, and/or supplying a product that was unsafe and defective;
- Designing, manufacturing, selling, and/or supplying a product that was unsafe for its intended uses;
- d. Designing, manufacturing, selling, and/or supplying a product that was unsafe for all its intended and foreseeable purposes and uses;
- Designing, manufacturing, selling, and/or supplying a product without necessary, visible, and/or proper warnings;
- f. Designing, manufacturing, selling, and/or supplying a product without adequate warnings;
- g. Designing, manufacturing, selling, and/or supplying a product containing
 DMAA that cause an unreasonable risk of occurrence of personal injury;
- Designing, manufacturing, selling, and/or supplying a product that failed to comply with relevant standards;
- i. Failing to properly test the product;
- j. Failing to warn;
- k. Failing to properly warn;
- 1. Failing to make the product safe for consumption;
- m. Failing to warn of the danger posed by the product;
- Failing to properly and/or adequately warn of the defects and/or other conditions noted in this paragraph;

- 64. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described, Decedent, sustained serious injuries and death. Plaintiff and Decedent required healthcare and services; incurred medical and related expenses; has suffered loss of wages and a complete capacity to earn wages in the future; diminished capacity for the enjoyment of life, a diminished quality of life, and other such damages. JESSICA DAVILA incurred direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
- 65. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff's Decedent, thereby entitling Plaintiff to exemplary damages so as to punish Defendants and deter them from similar conduct in the future.
- 66. By reason of ALL DEFENDANTS failure to conform to its duties and obligations under Section 402A of the Restatement of Torts (Second), as aforesaid, JESSICA DIANE DAVILA was caused to sustain the severe, devastating and permanent personal injuries listed above.
- 67. ALL DEFENDANTS failure to conform to their respective duties and obligations under Section 402A of the Restatement of Torts (Second) as aforesaid, increased the risk of harm in that it increased the likelihood that JESSICA DIANE DAVILA would die, as described above.

COUNT TWO Plaintiff v. All Defendants NEGLIGENCE

- 68. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.
- 69. Defendants owed Plaintiff and Plaintiff's Decedent a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling PRO. This duty included the duty not to introduce a product into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.
- 70. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiff's Decedent and the Public of the risks, dangers and adverse side effects of PRO.
- 71. Defendants breached their duties to DAVILA by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of PRO, including:
 - failing to adhere to and in violation of the relevant rules, regulations, and/or statutes related to the production of PRO;
 - failing to adhere to and in violation of the relevant rules, regulations and/or statutes related to the testing of PRO;
 - failing to adhere to and in violation of the relevant rules, regulations and/or statutes related to the presence of DMAA in PRO;
 - d. failing to adhere to and in violation of the relevant rules, regulations and/or statutes related to the sale and distribution of PRO;

- failing to use due care in the preparation and development of PRO to prevent the aforementioned risk of injuries to individuals when the product was ingested;
- failing to use due care in the design of PRO to prevent the aforementioned risk of injuries to individuals when the product was used;
- g. failing to use due care in the manufacture, inspection, and labeling of PRO to prevent the aforementioned risk of injuries to individuals who used the product;
- failing to use due care in the sale and marketing of PRO to prevent the
 aforementioned risk of injuries to individuals when the product was used; and
- i. being otherwise reckless, careless and/or negligent as aforesaid.
- 72. Despite the fact that Defendants knew or should have known that PRO caused could cause unreasonable and dangerous side effects which many users would be unable to remedy by any means, Defendants continued to promote and market PRO to consumers, including Plaintiff's Decedent.
- 73. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiff's Decedent, sustained injuries and death. Plaintiff and Plaintiff's Decedent has incurred medical and related expenses; has suffered loss of wages and a complete capacity to earn wages in the future; has suffered and will continue to suffer mental anguish; diminished capacity for the enjoyment of life; a diminished quality of life; and other such damages.
- 74. The aforesaid acts of negligence by Defendants increased the risk of harm that JESSICA DIANE DAVILA would die on or about November 14, 2011.

COUNT THREE Plaintiff v. All Defendants BREACH OF EXPRESS WARRANTY

- 75. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.
- 76. Defendants expressly represented to JESSICA DAVILA and other consumers that PRO was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.
- 77. Defendants knew or had reason to know that PRO did not conform to express representations that PRO was not as safe or as effective as represented, and that PRO produces serious adverse side effects. Such representations included: OxyELITE ProTM **absolutely** unmatched! as a product, and that the product was "safe and effective" among others.
- 78. PRO did not conform to Defendants' express representations because it is not safe, and has multiple and serious side effects, including hyperthermia, irregular heartbeat, seizures, heart attack, stroke, and kidney damage, among other things, and causes severe and permanent injuries.
- 79. Plaintiff's Decedent and other consumers relied upon Defendants' express warranties.

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- 80. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiff's Decedent suffered a needless and painful death.

 JESSICA DAVILA required healthcare and services; incurred medical and related expenses; suffered loss of wages and a completely diminished capacity to earn wages in the future;

 JESSICA DAVILA incurred direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
- 81. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff's Decedent, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

COUNT FOUR Plaintiff v. All Defendants BREACH OF IMPLIED WARRANTY

- 82. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.
- 83. The Defendants designed, tested, manufactured, packaged, marketed, distributed, promoted, and sold PRO.
- 84. At all relevant times, Defendants knew of the use for which PRO was intended and impliedly warranted the drug was of merchantable quality and safe and fit for such use.

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- 85. PRO was not of merchantable quality nor fit for its intended use, because it causes increased risk of serious injury and death.
- 86. Defendants breached the implied warranty that PRO was of merchantable quality and fit for such use.
- 87. Defendants were aware that consumers, including Plaintiff's Decedent, would use PRO as a supplement for good health.
- 88. JESSICA DAVILA and the community reasonably relied upon Defendants' judgment and expertise to sell PRO in that it was indeed of merchantable quality and safe and fit for its intended use.
- 89. Consumers, including DAVILA and the medical community, reasonably relied upon Defendants' implied warranty for PRO.
- 90. PRO reached consumers, including Plaintiff's Decedent, without substantial change in the condition in which it was manufactured and sold by Defendants.
- 91. Defendants breached their implied warranty to consumers, including Plaintiff's Decedent, as RO was not of merchantable quality or safe and fit for its intended use.
- 92. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, JESSICA DAVILA died a needless death. She required healthcare and services; incurred medical and related expenses.
- 93. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers.

FIRST CAUSE OF ACTION - WRONGFUL DEATH PLAINTIFF v. ALL DEFENDANTS

- 94. All of the foregoing paragraphs are incorporated by reference as though fully set forth at length herein.
- 95. Plaintiff SHIRLEY DAVILA is the Trustee ad Litem of the Estate of JESSICA DIANE DAVILA, plaintiff's decedent, who died on or about November 14, 2011.
- 96. There were no claims filed on behalf of the Estate of JESSICA DIANE DAVILA in the six months since her death.
- 97. Plaintiff SHIRLEY DAVILA now brings this action on behalf of the Estate of JESSICA DIANE DAVILA.
- 98. Pursuant to Pa.R.C.P. 2202(b), SHIRLEY DAVILA is the proper Trustee ad Litem for this wrongful death action.
 - 99. Plaintiff's decedent died without issue.
 - 100. SHIRLEY DAVILA resides at 619 Poplar Street, Abilene, Texas 79602.
- 101. As a result of the aforementioned tortious acts and/or omissions of each of the defendants, Plaintiff's decedents Wrongful Death beneficiaries have been required to spend money and incur obligations in an effort to treat and care for the aforementioned injuries to Plaintiff's decedent and have been deprived of the earnings and the value of the services of the decedent and have been deprived of the expected monetary contributions and the pecuniary value

20

of the services, society, comfort, guidance, and tutelage of the decedent during his life

expectancy.

102. Plaintiff claims damages for the monetary and pecuniary loss occasioned by the

death of Plaintiff's decedent, as well as, for reimbursement of hospital expenses, nursing

expenses, medical expenses, funeral expenses, burial expenses, and expenses of Estate

administration.

103. Plaintiff claims damages for the pecuniary losses sustained as a result of the

decedent's death including damages for the loss of the contributions, services, society and

comfort decedent would have provided had he survived.

Plaintiff brings this action by virtue of, inter alia, 42 Pa.C.S.A. § 8301 and claims

all damages encompassed thereby.

WHEREFORE, Plaintiff, SHIRLEY DAVILA, demands judgment in her favor and

against all defendants, jointly and severally, for compensatory damages in excess of the

arbitration limits in effect in Philadelphia County, Pennsylvania at the time this cause of action

was commenced.

Respectfully submitted,

WAPNER, NEWMAN, WIGRIZER,

BRECHER & MILLER, P.C.

BY: /s/ Steven G. Wigrizer

STEVEN G. WIGRIZER

JASON S. WEISS

Attorneys for Plaintiff

21

VERIFICATION

The undersigned, having read the attached which was prepared by my attorneys, hereby verifies that the information contained therein may include information furnished to my attorneys by individuals other than myself; that the language used therein is that of my attorneys, and that to the extent the information set forth therein is not known to me, I have relied upon my attorneys in taking this Verification. Subject to the above limitations, the information contained therein is true and correct to the best of my information, knowledge and belief, subject to the penalties imposed by 18 Pa. C.S. § 4904.

Shirley Davila

EXHIBIT B



EXHIBIT C

WEBER GALLAGHER SIMPSON STAPLETON FIRES & NEWBY LLP

July 12, 2012



Direct Dial: (267) 519-4974 Email: mmurray@wglaw.com

United States District Court Eastern District of Pennsylvania Attn: Clerk's Office U.S. Courthouse 601 Market Street, Room 2609 Philadelphia, PA 19106

RE: Estate of Jessica Diane Davila, et al vs USP Labs, LLC, et al

No.: U.S.D.C., E.D.PA., C.A., TBD

(Philadelphia County CCP No.: 120602113

Our File Number: 0064330

Dear Sir/Madam:

I represent the Defendants, USPLABS, LLC, General Nutrition Centers, Inc., and GNC Holdings, Inc. in the above-captioned matter. Enclosed please find a Notice of Removal on behalf of Defendants along with a Civil Cover Sheet, Designation Form, Disclosure Statement Forms and Case Management Track Designation Form. Kindly file this document of record and confirm filing of same via appropriate electronic means. I have also enclosed this firm's check in the amount of \$350.00 which represents payment of your filing fee.

If you have any questions or need any additional information, please feel free to contract the undersigned counsel.

Very truly yours,

William C\Mills, Esquire

WCM/mkm Enclosures

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS		ni isaangis madalaasinahalagalinah gaarya ya ya gaasanya ayuu yuun noo asiini noo uu uu uu u	g t yw drywnau yn arwynnau gygaldd i anargw.	DEFENDA	ANTS					***************************************
Shirley Davila, individually and as Trustee Ad Litem for the Estate of Jessica Diane Davila, deceased Taylor (b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)				USPLABS, GNC Holdin County of R	LLC, Gener igs, Inc. esidence of LAND CONI	First Lis (IN U	tion Centers, Inc., tted Defendant S. PLAINTIFF CASES TION CASES, USE THE		F THE	MARIANIZIA deser
(c) Attorney's (Firm Name, Steven G. Wigriz: St., Suite 2750, Philade	arket		C. Mills		nire, 2000 Marke 3 (215) 972-790		loor,	MAANA-III OO OO MAANA OO		
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VI. CAUSE OF ACTION 21 U.S.C. 301 et. seq. Brief Description of Cause alleged personal injury caused by dietary supplement										
VII. REQUESTED IN COMPLAINT		IS A CLASS ACTIO		DEMAN	D S		CHECK YES only if URY DEMAND:		complain	transparate and the second sec
VIII. RELATED CASE(S) IF ANY										
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UNITED STATES DISTRICT COURT

APPENDIX F

FOR THE EASTERN DISTRICT OF PENNSYLVANIA – DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 619 Poplar Street, Abilene, TX 79602		ivanino-menovisiuminamen-menovosiopse	
Address of Defendant: 10761 King William Drive, Dallas, TX 75220		on the state of the	
Place of Accident, Incident or Transaction: 901 W Ben White, Blvd., Austin, TX	(78704 (Use Reverse Side For Additional Space)	***************************************	
Does this civil action involve a nongovernmental corporate party with any parent c	orporation and any publicly held corporation o	owning 10%	or more or is stock?
(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Ci	/.P.7.1(a))	Yes 🛭	NoD
Does this case involve multidistrict litigation possibilities? RELATED CASE, IF ANY:		Yes□	No⊠
Case Number: Judge	Date Terminated		
ivil cases are deemed related when yes is answered to any of the following question	MIS:		
Is this case related to property included in an earlier numbered suit pending or w	ithm on year previously terminated action in th	nis court? Yes□	No⊠
. Does this case involve the same issue of fact or grow out of the same transaction	as a prior suit pending or within one year prev	iously termi	nated
action in this court?		Yes□	No⊠
. Does this case involve the validity of infringement of a patent already in suit or a	my earlier numbered case pending or within on	ne year previ	ously
terminated action in this court?		Yes	No⊠
CIVIL: (Place X in ONE CATEGORY ONLY) A. Federal Questions Cases: Indemnity Contract, Marine Contract, and All Other Contracts Description: Antitrust Antitrust Labor-Management Relations Civil Rights Habeas Corpus Securities Act(s) Cases Social Security Review Cases Well All other Federal Question Cases (Please specify) Federal Food, Drug and Cosmetic Act as amended by the Description a	B. Diversity Jurisdiction Cases: 1.	njury ease specify	
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certify that to my knowledge, the within case is not related to any case now pe	*		n this court
PATE: 7/12/2012	f	6579	ب در و در
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	3 VV		Attorney I.D.#

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

Shirley Davila, Individually and pursuant to Civil Action No: Pa.R.C.P. 2202(b) as Trustee Ad Litem for the Estate of Jessica Diane Davila, deceased,

٧.

General Nutrition Centers, Inc., GNC Holdings, Inc., and USPLABS, LLC

DISCLOSURE STATEMENT FORM

Pleas	e check one box:	
The second secon		of corporate party, , in the above listed civil action arent corporation and publicly held corporation that owns book.
	above listed civil acti	al corporate party, General Nutrition Centers, Inc., in the on has the following parent corporation(s) and publicly held was 10% or more of its stock:
	GNC Corporation	
7/12/2	.012	<u> </u>
Date		Signature
	Counsel for:	Defendants
corpo staten	(a) WHO MUST FILE: No rate party to an action ment that identifies any 10% or more of its storage.	dure 7.1 Disclosure Statement IONGOVERNMENTAL CORPORATE PARTY. A nongovernmental or proceeding in a district court must file two copies of a parent corporation and any publicly held corporation that ck or states that there is no such corporation. UPPLEMENTAL FILING. A party must: 1) file the Rule 7.1(a) statement with its first

appearance, pleading, petition, motion, response, or

other request addressed to the court, and

(2) promptly file a supplemental statement upon any change in the information that the statement requires.

Mechanisms Established to Assist in Securing Compliance with Federal Rule of Civil Procedure 7.1, Disclosure Statement

Effective January 1, 2007

Each complaint is reviewed at the time of filing for compliance with the requirements of Fed. R. Civ. P. 7.1.

For each Disclosure Statement Form that is filed by a nongovernmental corporate party identifying parent corporation(s) and publicly held corporation(s) that own 10% more of its stock, the corporation(s) identified are added to the automated conflict checking system in CM/ECF. The form is forwarded to the judge assigned to the case.

For each complaint that is filed with the required Disclosure Statement (copy attached), a notice is sent to the attorney requesting compliance with Fed. R. Civ. P. 7.1 and the filing of the Disclosure Statement Form. A copy of the notices is forwarded to the courtroom deputy clerk of the assigned judge.

- Documents filed subsequent to the complaint are reviewed for compliance with the Fed. R. Civ. P. 7.1. The above –referenced notice is sent to any attorney not in compliance with the requirements of Fed. R. Civ. P. 7.1 and a copy is forwarded to the courtroom deputy clerk of the assigned judge.
- In the event a financial disclosure form has not been received within 10 days of the date of the notice, the courtroom deputy clerk is notified. The courtroom deputy clerk will bring this matter to the attention of the assigned judge.

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

Shirley Davila, Individually and pursuant to Civil Action No: Pa.R.C.P. 2202(b) as Trustee Ad Litem for the Estate of Jessica Diane Davila, deceased.

V.

General Nutrition Centers, Inc., GNC Holdings, Inc., and USPLABS, LLC

DISCLOSURE STATEMENT FORM

Please	e check one box:				
gorganeration of the state of t	The nongovernmental corporate party, , in the above listed civil action does not have any parent corporation and publicly held corporation that owns 10% or more of its stock.				
\boxtimes	The nongovernmental corporate party, General Nutrition Centers, Inc., in the above listed civil action has the following parent corporation(s) and publicly held corporation(s) that owns 10% or more of its stock:				
	GNC Corporation				
7/12/2	012		Mahan		
Date	andiga nation and great an		Signature		
	Counsel for:	Defendants			
Feder	al Rule of Civil Proc	edure 7.1 Discl	osure Statement		

- (a) Who Must File: Nongovernmental Corporate Party. A nongovernmental corporate party to an action or proceeding in a district court must file two copies of a statement that identifies any parent corporation and any publicly held corporation that owns 10% or more of its stock or states that there is no such corporation.
 - (b) TIME FOR FILING; SUPPLEMENTAL FILING. A party must:
 - (1) file the Rule 7.1(a) statement with its first appearance, pleading, petition, motion, response, or other request addressed to the court, and

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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

Shirley Davila, Individually and pursuant to Civil Action No: Pa.R.C.P. 2202(b) as Trustee Ad Litem for the Estate of Jessica Diane Davila, deceased.

V.

General Nutrition Centers, Inc., GNC Holdings, Inc., and USPLABS, LLC

DISCLOSURE STATEMENT FORM

Please	e check one box:		
		have any paren	ty, GNC Holdings, Inc., in the above listed t corporation and publicly held corporation
government, and the second sec		corporation(s) a	ty, , in the above listed civil action has nd publicly held corporation(s) that owns
7/12/2	012		() William
Date	950 foreit (2000 (2000)		Signature
	Counsel for:	Defendants	

Federal Rule of Civil Procedure 7.1 Disclosure Statement

- (a) Who Must File: Nongovernmental Corporate Party. A nongovernmental corporate party to an action or proceeding in a district court must file two copies of a statement that identifies any parent corporation and any publicly held corporation that owns 10% or more of its stock or states that there is no such corporation.
 - (b) TIME FOR FILING; SUPPLEMENTAL FILING. A party must:
 - (1) file the Rule 7.1(a) statement with its first appearance, pleading, petition, motion, response, or other request addressed to the court, and

(2) promptly file a supplemental statement upon any change in the information that the statement requires.

Mechanisms Established to Assist in Securing Compliance with Federal Rule of Civil Procedure 7.1, Disclosure Statement

Effective January 1, 2007

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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

Shirley Davila, Individually and pursuant to Civil Action No: Pa.R.C.P. 2202(b) as Trustee Ad Litem for the Estate of Jessica Diane Davila, deceased.

V.

General Nutrition Centers, Inc., GNC Holdings, Inc., and USPLABS, LLC

DISCLOSURE STATEMENT FORM

Pleas	se check one box:
	The nongovernmental corporate party, GNC Holdings, Inc., in the above listed civil action does not have any parent corporation and publicly held corporation that owns 10% or more of its stock.
	The nongovernmental corporate party, , in the above listed civil action has the following parent corporation(s) and publicly held corporation(s) that owns 10% or more of its stock:
7/12/2	2012 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Date	Signature \
	Counsel for: Defendants
corpoi staten	ral Rule of Civil Procedure 7.1 Disclosure Statement (a) Who Must File: Nongovernmental rate party to an action or proceeding in a district court must file two copies of a ment that identifies any parent corporation and any publicly held corporation that 10% or more of its stock or states that there is no such corporation. (b) TIME FOR FILING; SUPPLEMENTAL FILING. A party must:

file the Rule 7.1(a) statement with its first

other request addressed to the court, and

appearance, pleading, petition, motion, response, or

(1)

(2) promptly file a supplemental statement upon any change in the information that the statement requires.

Mechanisms Established to Assist in Securing Compliance with Federal Rule of Civil Procedure 7.1, Disclosure Statement

Effective January 1, 2007

Each complaint is reviewed at the time of filing for compliance with the requirements of Fed. R. Civ. P. 7.1.

For each Disclosure Statement Form that is filed by a nongovernmental corporate party identifying parent corporation(s) and publicly held corporation(s) that own 10% more of its stock, the corporation(s) identified are added to the automated conflict checking system in CM/ECF. The form is forwarded to the judge assigned to the case.

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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

Shirley Davila, Individually and pursuant to Civil Action No: Pa.R.C.P. 2202(b) as Trustee Ad Litem for the Estate of Jessica Diane Davila, deceased.

V.

General Nutrition Centers, Inc., GNC Holdings, Inc., and USPLABS, LLC

Please check one box:

DISCLOSURE STATEMENT FORM

\boxtimes		e any parent co	rty, USPLABS, LLC, in the above listed civil rporation and publicly held corporation that
and anticommunity of the state		corporation(s) a	rty, , in the above listed civil action has and publicly held corporation(s) that owns
7/12/2	012		Charge
Date			Signature
	Counsel for:	Defendants	

Federal Rule of Civil Procedure 7.1 Disclosure Statement

- (a) Who Must File: Nongovernmental corporate Party. A nongovernmental corporate party to an action or proceeding in a district court must file two copies of a statement that identifies any parent corporation and any publicly held corporation that owns 10% or more of its stock or states that there is no such corporation.
 - (b) TIME FOR FILING; SUPPLEMENTAL FILING. A party must:
 - (1) file the Rule 7.1(a) statement with its first appearance, pleading, petition, motion, response, or other request addressed to the court, and

(2) promptly file a supplemental statement upon any change in the information that the statement requires.

Mechanisms Established to Assist in Securing Compliance with Federal Rule of Civil Procedure 7.1, Disclosure Statement

Effective January 1, 2007

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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

Shirley Davila, Individually and pursuant to Civil Action No: Pa.R.C.P. 2202(b) as Trustee Ad Litem for the Estate of Jessica Diane Davila, deceased.

V.

General Nutrition Centers, Inc., GNC Holdings, Inc., and USPLABS, LLC

Please check one hov:

DISCLOSURE STATEMENT FORM

11000	o shook one box.
	The nongovernmental corporate party, USPLABS, LLC, in the above listed civil action does not have any parent corporation and publicly held corporation that owns 10% or more of its stock.
	The nongovernmental corporate party, , in the above listed civil action has the following parent corporation(s) and publicly held corporation(s) that owns 10% or more of its stock:
7/12/2	012 MMAhar
Date	Signature
	Counsel for: Defendants
gree g	

Federal Rule of Civil Procedure 7.1 Disclosure Statement

- (a) WHO MUST FILE: NONGOVERNMENTAL CORPORATE PARTY. A nongovernmental corporate party to an action or proceeding in a district court must file two copies of a statement that identifies any parent corporation and any publicly held corporation that owns 10% or more of its stock or states that there is no such corporation.
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 - (1) file the Rule 7.1(a) statement with its first appearance, pleading, petition, motion, response, or other request addressed to the court, and

(2) promptly file a supplemental statement upon any change in the information that the statement requires.

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Effective January 1, 2007

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APPENDIX I

CIVIL ACTION

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Shirley Davila, individually and pursuant to :

Pa.R.C.P. 2202(b) as Trustee Ad Litem for

Telephone	FAX Numb	per	E-Mail Address		
215-972-7900	215-564-76	99	wmills@wglaw.com		
7/12/2012 Date	William C. Attorney-a	Mills, Esquire	Defendants Attorney for	www.communications.	
(f) Standard Management – Cases that do not fall into any one of the other tracks.				(X)	
(e) Special Management – Case commonly referred to as con the court. (See reverse side of management cases.)	nplex and that	need special or intens	se management by	()
(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos				*majed)
(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2				()
b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits				()
(a) Habeas Corpus – Cases brou	ght under 28 l	U.S.C. §2241 through	n [§] 2255.	()
SELECT ONE OF THE FOLL	OWING CA	SE MANAGEMEN	Γ TRACKS:		
In accordance with the Civil Juplaintiff shall complete a case Milling the complaint and serve a side of this form.) In the even designation, that defendant shall the plaintiff and all other parties which that defendant believes the	Management Topy on all det that a defer, with its first, a case man	Frack Designation For fendants. (See §1:03 adant does not agree t appearance, submit agement track design	rm in all civil cases at the of the plan set forth on the with the plaintiff regard to the clerk of court and	time reve ing s serve	e of erse said on
the Estate of Jessica Diane Davil v. General Nutrition Centers, In Holdings, Inc., and USPLAE	ic., GNC	:	NO.		

(Civ. 660) 10/02

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SHIRLEY DAVILA, individually and pursuant to Pa.R.C.P. 2202(b) as Trustee Ad Litem for the Estate of JESSICA DIANE DAVILA, deceased

CIVIL ACTION

NO.

*

Plaintiff,

*

GENERAL NUTRITION CENTERS, INC., GNC HOLDINGS, INC., and USPLABS, LLC

V.

*

Defendants

eiendants

NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §1331, §1441 and §1446, Petitioners, USPLABS, LLC, GENERAL NUTRITION CENTERS, INC., and GNC HOLDINGS, INC. petition to move this action from the Court of Common Pleas of Philadelphia County, PA to the United States District Court for the Eastern District of Pennsylvania and in support thereof avers as follows:

STATE COURT ACTION

- 1. This action for removal is currently before the Court of Common Pleas of Philadelphia County, PA at civil docket no. 126002113.
- 2. Plaintiff in this case is Shirley Davila, individually and as Trustee Ad Litem for the Estate of Jessica Diane Davila.
- 3. Petitioners are USPLABS, LLC, General Nutrition Centers, Inc., and GNC Holdings, Inc.

- 4. On June 18, 2012, Plaintiff filed a Civil Action Complaint in the Court of Common Pleas of Philadelphia County, PA. A true and correct copy of the Complaint is attached hereto as Exhibit "A".
- 5. On June 19, 2012, Jason Scott Weiss, Esquire entered his appearance on behalf of Plaintiff. A true and correct copy of the Entry of Appearance is attached hereto as Exhibit "B".
- 6. On June 21, 2012, Jason Scott Weiss, Esquire filed a Motion for Admission Pro Hac Vice. A true and correct copy of the Motion for Admission Pro Hac Vice is attached hereto as Exhibit "C".
- 7. The Motion for Admission Pro Hac Vice was purportedly served on Defendants, General Nutrition Centers, Inc. and GNC Holdings, Inc. by personal service on June 22, 2012. A true and correct copy of the Affidavit of Service of Motion is attached hereto as Exhibit "D".
- 8. Plaintiff purportedly served Defendants, General Nutrition Centers, Inc. and GNC Holdings, Inc. with the Complaint by personal service on June 19, 2012. A true and correct copy of the Affidavit of Service is attached hereto as Exhibit "E".
- 9. Plaintiff purportedly served Defendant, USPLABS, LLC, with the Complaint by personal service on June 21, 2012. A true and correct copy of the Affidavit of Service is attached hereto as Exhibit "F".
- 10. This Notice of Removal is timely as it is filed within 30 days of Defendants' receipt of the Complaint. Foster v. Mutual Fire, Marine & Inland Inc. Co., 986 F.2d 48, 54 (3d Cir. 1993); 28 U.S.C. §1446(b).

FEDERAL JURISDICTION

- 11. The United States District Court for the Eastern District of Pennsylvania has original jurisdiction over this action pursuant to 28 U.S.C. §1331 as this action raises a federal question that arises under the laws of the United States.
- 12. The Complaint alleges that Plaintiff's decedent died as the result of malignant hyperthermia due to consumption of a thermogenic diet pill, OxyElite Pro (hereinafter "PRO") allegedly manufactured, distributed, packaged, delivered, sold and marketed by Defendant USP.

 See generally Complaint, Exhibit "A" and at ¶ 5, 10.
- 13. According to the Complaint, the Plaintiff bases her claim for relief against the Defendants upon numerous violations of the Federal Food, Drug and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act of 1994. 21 U.S.C. § 301 et. seq.
- 14. The Complaint alleges that PRO is "an adulterated dietary supplement as that term is defined in the Food, Drug and Cosmetic Act" due to the ingredient Dimethylamylamine.

 See Complaint, Exhibit "A" at ¶ 42-49.
- 15. The Complaint alleges that Defendants violated the Federal Food, Drug and Cosmetic Act by "improperly" claiming "that the PRO product is a legal dietary supplement".

 See Complaint, Exhibit "A" at ¶ 41.
- 16. The Complaint alleges that an ingredient in PRO, Dimethylamylamine was "manufactured synthetically" and "unlawfully on the market" in violation of the Federal Food, Drug and Cosmetic Act as amended by the Dietary Supplement Health and Education Act of 1994. See Complaint, Exhibit "A" at ¶ 45.
- 17. The Complaint alleges that the Defendants violated "relevant rules, regulations and/or statutes" related to PRO by "engaging in the manufacturing, distribution, selling and/or

supplying of PRO" which caused the Plaintiff to suffer damages. See Complaint, Exhibit "A" at

¶ 49.

18. This Court has jurisdiction over this action pursuant to 28 U.S.C. ¶ 1331 as

Plaintiff's Complaint raises issues of federal law and prosecution of Plaintiff's claims against

Defendants will require construction of the Federal Food, Drug and Cosmetic Act as amended by

the Dietary Supplement Health and Education Act of 1994.

19. All Defendants consent to the removal of this action to this Court.

20. A copy of all process, pleadings, and orders served upon the Defendants is filed

with this Notice.

21. Concurrent with this filing, Defendants are providing notice of this removal to the

Court of Common Pleas of Philadelphia County, Pennsylvania, pursuant to 28 U.S.C. § 1446(d).

22. This action is removed pursuant to 28 U.S.C. ¶ 1441.

WHEREFORE, Defendants respectfully request that this action now pending in the Court

of Common Pleas of Philadelphia County, Pennsylvania be removed to this Court.

Respectfully submitted.

WEBER GALLAGHER SIMPSON STAPLETON FIRES & NEWBY LLP

2000 Market Street, 13th Floor Philadelphia, PA 19103

(215) 972-7900

(215) 564-7699 (Fax)

Bv:

William C. Mills, Esquire

wmills@wgtaw.com
Attorney for Defendants

Dated: July 12, 2012

EXHIBIT D



IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION; THIS DOCUMENT APPLIES TO: MARK SHURTLEFF, ATTORNEY GENERAL OF THE STATE OF UTAH ex rel. THE STATE OF UTAH v. GLAXOSMITHKLINE, LLC, formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; STATE OF LOUISIANA v. GLAXOSMITHKLINE, LLC, formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; GLAXOSMITHKLINE, PLC

MDL NO. 1871 07-MD-01871,CIVIL ACTION NO. 11-2915,CIVIL ACTION NO. 11-3521

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

2012 U.S. Dist. LEXIS 48319

April 4, 2012, Decided April 4, 2012, Filed

SUBSEQUENT HISTORY: Transferred to In re Avandia Mktg., Sales Practices & Prods. Liab. Litig., 2012 U.S. Dist. LEXIS 50480 (J.P.M.L., Apr. 10, 2012)
Transferred by Bowerman v. Glaxo Smith Kline, LLC(In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.), 2012 U.S. Dist. LEXIS 82967 (J.P.M.L., June 14, 2012)

PRIOR HISTORY: *In re Avandia Mktg., 2012 U.S. Dist. LEXIS 26419 (J.P.M.L., Feb. 27, 2012)*

COUNSEL: [*1] For PATRICK A. JUNEAU (2:07-md-01871-CMR), Special Master: PATRICK A. JUNEAU, JR., LAFAYETTE, LA.

For BRUCE P. MERENSTEIN (2:07-md-01871-CMR), Special Master: BRUCE P. MERENSTEIN, LEAD ATTORNEY, SCHNADER HARRISON SEGAL & LEWIS, PHILADELPHIA, PA.

For ANDREW A. CHIRLS, COMMON BENEFIT FUND ADMINISTRATOR (2:07-md-01871-CMR), Administrator: ANDREW A. CHIRLS, LEAD ATTORNEY, HAINES & ASSOCIATES,

PHILADELPHIA, PA.

For PLAINTIFFS' STEERING COMMITTEE (2:07-md-01871-CMR), Amicus: BILL ROBINS, III, LEAD ATTORNEY, HEARD ROBINS CLOUD & LUBEL LLP, SANTA FE, NM; JASON E. DUNAHOE, HEARD ROBINS CLOUD & BLACK LLP, HOUSTON, TX; PAUL R. KIESEL, KIESEL BOUCHER & LARSON, BEVERLY HILLS, CA; TURNER W. BRANCH, BRANCH LAW FIRM, ALBUQUERQUE, NM.

For MARK SHURTLEFF, ATTORNEY GENERAL OF THE STATE OF UTAH EX REL. THE STATE OF UTAH (2:11-cv-02915-CMR), Plaintiff: BILL ROBINS, III, JUSTIN ROSS KAUFMAN, LEAD ATTORNEYS, HEARD ROBINS CLOUD & LUBEL LLP, SANTA FE, NM; JEFFREY D. GOOCH, LEAD ATTORNEY, SPENCE MORIARITY & SCHUSTER, SALT LAKE CITY, UT; L. MICHAEL MESSINA, LEAD ATTORNEY, LAW OFFICE OF L. MICHAEL MESSINA, PA, ALBUQUERQUE, NM; ROBERT C. MORTON, LEAD ATTORNEY, UTAH ATTORNEY

GENERAL'S OFFICE, UTAH MEDICAID FRAUD CONTROL [*2] UNIT, SALT LAKE CITY, UT.

For GLAXOSMITHKLINE, formerly known as SMITHKLINE BEECHAM (2:11-cv-02915-CMR), ADAM Defendant: В. MICHAELS, ATTORNEY, PEPPER HAMILTON LLP, NEW YORK, NY; BARRY H. BOISE, NINA M. GUSSACK, LEAD ATTORNEYS, PEPPER **HAMILTON** PHILADELPHIA, PA; JOHN A. ANDERSON, LEAD ATTORNEY, STOEL RIVES (UT), SALT LAKE CITY, UT; SCOTT S. NEWMAN, LEAD ATTORNEY, STOEL RIVES, SALT LAKE CITY, UT.

For STATE OF LOUISIANA (2:11-cv-03521-CMR), Plaintiff: ALLAN KANNER, CONLEE SCHELL WHITELEY, LEAD ATTORNEYS, KANNER & WHITELEY, LLC, NEW ORLEANS, LA; DEBORAH R. TROTTER, LEAD ATTORNEY, KANNER & WHITELEY LLC, NEW ORLEANS, LA; EDMOND WADE SHOWS, JOHN CARROLL WALSH, LEAD ATTORNEYS, SHOWS CALI BERTHELOT & WALSH LLP, BATON ROUGE, LA; JAMES DAVID CALDWELL, LEAD ATTORNEY, LOUISIANA DEPT OF JUSTICE, BATON ROUGE, LA; THOMAS ALLEN USRY, LEAD ATTORNEY, USRY WEEKS & MATTHEWS, NEW ORLEANS, LA.

For GLAXOSMITHKLINE LLC, formerly known as SMITHKLINE BEECHAM CORPORATION, doing as GLAXOSMITHKLINE (2:11-cv-03521-CMR), Defendant: ANTHONY VALE, LEAD ATTORNEY, FRANCIS X. LANE, PEPPER HAMILTON LLP, PHILADELPHIA, PA; DOUGLAS J. MOORE, LEAD ATTORNEY, IRWIN FRITCHIE URGUHART & MOORE LLC, NEW ORLEANS, [*3] LA; JAMES B. IRWIN, V, LEAD ATTORNEY, IRWIN FRITCHIE URQUHART & MOORE LLC, NEW ORLEANS, LA; KELLY G. JUNEAU, LEAD ATTORNEY, IRWIN, FRITCHIE, URQUHART & MOORE, LLC (NEW ORLEANS), NEW ORLEANS, LA; HEDYA ARYANI, PEPPER & HAMILTON, LLP. PHILADELPHIA, PA.

For GLAXOSMITHKLINE, PLC (2:11-cv-03521-CMR), Defendant: DOUGLAS J. MOORE, LEAD ATTORNEY, IRWIN FRITCHIE URGUHART & MOORE LLC, NEW ORLEANS, LA; JAMES B. IRWIN, V, LEAD ATTORNEY, IRWIN FRITCHIE URQUHART & MOORE LLC, NEW ORLEANS, LA; KELLY G. JUNEAU, LEAD ATTORNEY, IRWIN,

FRITCHIE, URQUHART & MOORE, LLC (NEW ORLEANS), NEW ORLEANS, LA.

JUDGES: HON. CYNTHIA M. RUFE, J.

OPINION BY: CYNTHIA M. RUFE

OPINION

MEMORANDUM OPINION

Rufe, J.

I. BACKGROUND

In these actions, filed on behalf of the states of Utah and Louisiana, Plaintiffs (collectively, "the States") allege that Defendant, GlaxoSmithKline ("GSK"), violated state consumer-protection statutes and committed state-law torts. In essence, Plaintiffs allege that Medicaid funds were improperly dispersed to Utah and Louisiana Medicaid participants and suppliers for the non-medically appropriate use of the diabetes drug Avandia because of fraudulent and deceptive practices by GSK that misrepresented the safety and efficacy of Avandia. [*4] The cases were filed in the applicable state courts, removed to federal court by GSK, and transferred to this Court by the Judicial Panel on Multidistrict Litigation. GSK argues that removal was proper in these cases because this Court has federal-question jurisdiction pursuant to 28 U.S.C. § 1331; in the Louisiana case, GSK also argues that removal was proper pursuant to 28 U.S.C. § 1332 because the true parties in interest to the dispute are of diverse citizenship and the amount in controversy exceeds \$75,000. The States seek to have the cases remanded to the state courts.

II. STANDARD OF REVIEW

Removal of a civil action from state to federal court is proper only if the action initially could have been brought in federal court. The removal statutes "are to be strictly construed against removal and all doubts should be resolved in favor of remand." 28 U.S.C. § 1331 grants federal district courts original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1332 provides that the federal courts have original jurisdiction over "all civil actions where the matter in controversy exceeds the sum or value of \$75,000, [*5] exclusive of interest and costs,

and is between . . . citizens of different States."⁴ As the party removing the case, GSK has the burden to prove that federal jurisdiction is proper at all stages of the litigation.⁵

- 1 28 U.S.C. § 1441(a).
- 2 Boyer v. Snap-On Tools Corp., 913 F.2d 108, 111 (3d Cir. 1990).
- 3 28 U.S.C. § 1331.
- 4 28 U.S.C. § 1332(a).
- 5 Samuel-Bassett v. KIA Motors Am., Inc., 357 F.3d 392, 396 (3d Cir. 2004).

III. DISCUSSION

A. Federal Question Jurisdiction

Although there is no "mechanical test for determining when an 'action aris[es] under'6 federal law," for purposes of jurisdiction, it is generally accepted that the "well-pleaded complaint [must] establish[] either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law."⁷

- 6 See Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal., 463 U.S. 1, 8, 103 S. Ct. 2841, 77 L. Ed. 2d 420 (1983).
- 7 Empire Healthchoice Assurance, Inc. v. McVeigh, 547 U.S. 677, 690, 126 S. Ct. 2121, 165 L. Ed. 2d 131 (2006).

"Arising under" federal-question jurisdiction is generally appropriate in two types of actions. The first, most common, category involves suits in which the plaintiff pleads a cause of action [*6] created by federal law.⁸ In the second "slim category of cases," a plaintiff pleads a state law cause of action that "implicate[s] significant federal issues" or "turn[s] on substantial questions of federal law," and therefore contains an "embedded federal issues.]."

- 8 See, e.g., Am. Well Works Co. v. Layne & Bowler Co., 241 U.S. 257, 260, 36 S. Ct. 585, 60 L. Ed. 987 (1916); Metro. Life Ins. Co. v. Price, 501 F.3d 271, 276 (3d Cir. 2007) ("Federal question jurisdiction exists when the plaintiff's well-pleaded complaint establishes that federal law creates the cause of action.") (internal quotation omitted).
- 9 Empire, 547 U.S. at 701.

10 Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 312, 318, 125 S. Ct. 2363, 162 L. Ed. 2d 257 (2005).

In both categories, every putative federal-question case must adhere to the "well-pleaded complaint" rule. Under that rule, a suit "arises under' federal law 'only when the plaintiff's statement of his own cause of action shows that it is based upon [federal law]."11 The existence of a federal defense to a state-law cause of action will not suffice; 12 instead, the plaintiff's well-pleaded complaint must include, within its four corners, either an explicit federal cause of action or a state-law cause [*7] of action that contains an embedded federal question that is both substantial and disputed. "13 Moreover, "[t]he fact that a complaint mentions, or even incorporates a federal law, does not determine whether it 'arises under' the Constitution, laws or treaties of the United States."14

- 11 Vaden v. Discover Bank, 556 U.S. 49, 60, 129 S. Ct. 1262, 173 L. Ed. 2d 206 (2009) (quoting Louisville & Nashville R.R. v. Mottley, 211 U.S. 149, 152, 29 S. Ct. 42, 53 L. Ed. 126 (1908)).
- 12 It is well-established that a federal defense does not provide a basis for removal. "even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue." Caterpillar Inc. v. Williams, 482 U.S. 386, 393, 107 S. Ct. 2425, 96 L. Ed. 2d 318 (1987); United Jersey Banks v. Parell, 783 F.2d 360, 365 (3d Cir. 1986). See also Merrell Dow Pharm., Inc. v. Thompson, 478 U.S. 804, 813, 106 S. Ct. 3229, 92 L. Ed. 2d 650 (1986) ("[T]he mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction.").
- 13 See, e.g., Mottley, 211 U.S. at 152,
- 14 Walker v. Family Med. Ctr. of Charleston, No. 06-00634, 2007 U.S. Dist. LEXIS 3835, 2007 WL 149001, at *2 (S.D. W. Va. Jan. 18, 2007); see also Fairfax Fin. Holdings Ltd. v. S.A.C. Capital Mgmt., LLC, No. 06-4197, 2007 U.S. Dist. LEXIS 39214, 2007 WL 1456204, at *3 (D.N.J. May 15, 2007) [*8] ("The Complaint does not 'necessarily raise' a federal question because it alleges predicate violations of both federal and state law.").

Jurisdiction will lie only if three conditions are met:

1) the case necessarily raises a federal issue, 2) the federal issue is substantial and in actual dispute, and 3) the exercise of federal jurisdiction will not disturb "any congressionally approved balance of federal and state judicial responsibilities." ¹⁵ If the dispute is fact-bound and does not rely solely on a determination of federal law, remand is appropriate. ¹⁶

15 Grable, 545 U.S. at 314.

16 Empire, 547 U.S. at 691-93 (holding that federal subject-matter jurisdiction was lacking in a case in which a health insurance carrier for federal employees brought suit seeking reimbursement of benefits on the ground that the enrollee had recovered damages for his injuries in a state court action).

Here, the States have asserted only state-law causes of action.¹⁷ GSK argues that the cases involve embedded federal questions because: 1) the States' obligation to pay for Avandia is rooted in the federal Medicaid statutes; and 2) whether GSK misrepresented Avandia requires interpretation of decisions by the [*9] federal Food and Drug Administration ("FDA").18 In the Utah case, GSK argues that because the federal Medicaid program requires Utah to pay for a "covered outpatient drug." and because the FDA approved the use Avandia for treatment of type 2 diabetes at the relevant times, Avandia was a covered drug and federal law required Utah to pay for it. Therefore, according to GSK, Utah's claim that GSK fraudulently induced all Avandia presecriptions in effect challenges Avandia's status as an approved and covered drug under federal law. 19 Similarly, in the Louisiana case, GSK argues that Louisiana's effort to compel GSK to provide a refund for every state-paid Avandia prescription requires the State to prove a basis under federal law to remove Avandia as a covered drug.20 However, as the Court reads the Complaints, the States do not allege that Avandia is not a covered drug under the federal Medicaid statute. The States allege that GSK's fraudulent and deceptive actions caused physicians to prescribe Avandia instead of safer and less expensive drugs.²¹ The issues of federal law do not predominate. Instead, the Court finds that disputed issues of state law predominate and that those issues are [*10] better suited to resolution by the state courts.²²

17 Indeed, the States are insistent in the Complaints that no federal claims are implicated.

For example, the Utah Complaint alleges that:

The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against Defendant. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy which is founded upon federal law. The issues presented in the allegations of the instant Complaint do not implicate significant federal issues; do not turn on the substantial federal interpretation of federal law; nor do they raise a substantial federal question. Indeed, Plaintiff expressly avers that the only causes of action claimed, and the only remedies sought herein, are for those founded upon the statutory, common, and decisional laws of the State of Utah. Further, assertion of federal jurisdiction over the claims made herein would improperly disturb congressionally approved balance [*11] of federal and responsibilities. Accordingly, any improvident and dilatory attempt by Defendant to remove this case to federal court would be without a reasonable legal basis in fact or law.

Utah Complaint at ¶ 6. The Louisiana Complaint, with similar sentiment but more brevity, alleges that the claims "arise exclusively under Louisiana law." Louisiana Complaint at ¶ 6.

- 18 See, e.g., Mem. in Supp. Mot. to Remand, Ex. B, Civil Action No. 11-2915 ¶ 14-15, 20, 25.
- 19 GSK Resp. in Civil Action No. 11-2915 (Doc. No. 7) at 1.
- 20 GSK Resp. in Civil Action No. 11-3521

(Doc. No. 6) at 2.

21 See New Mexico v. Ortho-McNeil-Janssen Pharms., Inc., No. 08-779, 2009 U.S. Dist. LEXIS 116524, at *7 (D.N.M. Jan. 26, 2009) (holding that "[c]laiming that Defendants wrongly triggered the State's obligation to pay for Risperdal is completely different than claiming that the State should not have such an obligation as a matter of law, despite the requirements of the federal Medicaid statute).

22 See generally *Pennsylvania v. Eli Lilly & Co., Inc., 511 F. Supp. 2d 576 (E.D. Pa. 2007)* (Pratter, J.).

GSK also argues that the States repeatedly invoked the federal Food, Drug, and Cosmetic Act ("FDCA")²³ in the Complaints, [*12] including allegations that the FDA cited GSK for violations of the law in connection with its marketing of Avandia. Although Plaintiffs indeed so allege, "[t]he mere presence of a federal standard embedded in a state law cause of action is not sufficient to warrant federal subject matter jurisdiction where there is no federal remedy for a violation of the federal statute."24 These allegations will not establish the States' ability to recover under their state-law claims; instead, these allegations relate to possible evidence to support the state-law claims.²⁵ After careful consideration, this Court finds that the cases brought by the States do not fall within that narrow class of cases in which federal jurisdiction may be found when only state-law causes of action are asserted.

23 21 U.S.C. § 301, et seq.

24 Pennsylvania, 511 F. Supp. 2d at 584 n. 3, 584-85 (E.D. Pa. 2007) (quoting Empire, 547 U.S. at 701, and citing Merrell Dow, 478 U.S. at 810-14). The fact that federal funds pay for part of the cost under the Medicaid program is similarly insufficient to confer federal jurisdiction. See id. 25 See New Mexico, No. 08-779, U.S. Dist. LEXIS 116524, at *7.

B. Diversity Jurisdiction

It is well [*13] established that a state is not considered a citizen for purposes of diversity jurisdiction.26 GSK argues in the Louisiana case, however, that the real party in interest is not the State but the Louisiana Department of Health and Hospitals ("LDHH"), that LDHH does not qualify as a state agency but is instead simply a citizen of Louisiana, and therefore

that diversity jurisdiction exists (as the amount in controversy is considerably more than \$75,000). The Court disagrees. Even if LDHH is the real party in interest, which GSK has not established, LDHH is a state agency for purposes of diversity jurisdiction.

26 Harris v. Pa. Tpk. Comm'n, 410 F.2d 1332, 1333 n. 1 (3d Cir. 1969) ("Since neither a state nor its alter ego is a citizen for purposes of diversity jurisdiction, a suit between a state, or its alter ego, and a citizen of another state is not a suit between citizens of different states and diversity jurisdiction does not exist.").

"Questions concerning the citizenship of state agencies for purposes of diversity are unavoidably linked to questions of agency immunity under the *Eleventh Amendment*. Despite the differing policies underlying the two inquiries, they are almost identical."²⁷ [*14] The courts of the Fifth Circuit have held consistently that LDHH is a state agency for *Eleventh Amendment* purposes.²⁸ GSK has given this Court no reason to conclude that LDHH should be treated differently for purposes of removal jurisdiction here.²⁹

Pennsylvania Human Relations Comm'n v. US Air, 615 F. Supp. 75, 77 (W.D. Pa. 1985); see also Blake v. Kline, 612 F.2d 718, 726-27 (3d Cir. 1979). The Fifth Circuit applies essentially the same standard. See Tradigrain, Inc. v. Miss. State Port Auth., 701 F.2d 1131, 1132 (5th Cir. 1983). See, e.g., Pechon v. Louisiana Dep't of Health & Hosps., No. 08-664, 2009 U.S. Dist. LEXIS 65376, 2009 WL 2046766 (E.D. La. July 14, 2009), aff'd in part, appeal dismissed in part, Pechon v. Louisiana Dep't of Health & Hosps., 368 F. App'x 606 (5th Cir. 2010). Accord Darlak v. Bobear, 814 F.2d 1055, 1060 (5th Cir. 1987) (holding that then-department of Health and Human Resources was a state agency for Eleventh Amendment purposes).

29 See Batton v. Georgia Gulf, 261 F. Supp. 2d 575, 593 (M.D. La. 2003) (holding that in determining diversity jurisdiction, "neither side disputes the status of LDHH as an arm of the state.").

IV. CONCLUSION

"An assertion of a violation of the FDCA as an element [*15] of a state tort claim is not a sufficiently

substantial federal issue to confer federal question jurisdiction."³⁰ GSK has not established that legal interpretations of the FDCA or the federal Medicaid statute predominate over the state-law issues to be determined in these cases, or that the parties are of diverse citizenship. The cases therefore will be remanded for lack of subject-matter jurisdiction. Because the question of the propriety of removal in cases such as these has been resolved differently within the federal courts, the Court does not find a basis for awarding costs to the States.³¹

30 In re Avandia Mktg., Sales Practices and Prods. Litig., 624 F. Supp. 2d 396, 415-16 (citing Merrell Dow, 478 U.S. 804, 106 S. Ct. 3229, 92 L. Ed. 2d 650).

31 Compare, e.g., Arkansas v. Astrazenca Pharms., L.P., No. 08-00601, 2008 U.S. Dist. LEXIS 67306, 2008 WL 3992746 (E.D. Ark. Aug. 25, 2008); Pennsylvania, 511 F. Supp. 2d 576; South Carolina v. Janssen Pharm., Inc., No. 07-1452, 2007 U.S. Dist. LEXIS 49904, 2007 WL 2022173 (D.S.C. July 10, 2007); Utah v. Eli Lilly & Co., 509 F. Supp. 2d 1016 (D. Utah 2007); Alaska v. Eli Lilly & Co., No. 06-88, 2006 U.S. Dist. LEXIS 52783, 2006 WL 2168831 (D. Alaska July 28, 2006) with State of Alaska v. Janssen Ortho LLC, No. 110002 (D. Alaska Apr. 29, 2011) (transcript of oral [*16] ruling denying motion to remand); In re Zyprexa Prods. Liab. Litig., 375 F. Supp. 2d 170 (E.D.N.Y. 2005).

Appropriate orders will be entered.

ORDER

AND NOW, this 4th day of April 2012, upon consideration of the plaintiff's Motion to Remand and the defendant's opposition thereto, it is hereby **ORDERED** that the Motion is **GRANTED**. This Court lacking subject-matter jurisdiction, the action is **REMANDED** to the Third Judicial District Court of Salt Lake County, West Jordan Department, State of Utah, Civil No.100423795.

It is so ORDERED.

BY THE COURT:

/s/ Cynthia M. Rufe

CYNTHIA M. RUFE, J.

ORDER

AND NOW, this 4th day of April 2012, upon consideration of the plaintiff's Motion to Remand and the defendant's opposition thereto, it is hereby **ORDERED** that the Motion is **GRANTED**. This Court lacking subject-matter jurisdiction, the action is **REMANDED** to the 19th Judicial District Court for the Parish of East Baton Rouge, State of Louisiana, Number C5993553 Division D.

It is so ORDERED.

BY THE COURT:

/s/ Cynthia M. Rufe

CYNTHIA M. RUFE, J.